Patent

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: HENDERSON, CHRISTOPHER P.

Application No.: 10/810958

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Confirmation No.: 9828 Group Art Unit

3772

Filed: Title:

NON-ELASTOMERIC RESPIRATOR MASK THAT HAS DEFORMABLE CHEEK

PORTIONS

BRIEF ON APPEAL

Mail Stop: Appeal Brief-Patents Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

CERTIFICATE OF TRANSMISSION [37 CFR § 1.8(a)]

I hereby certify that this correspondence is being transmitted to United Stafes Patent and Trademark Office on the date shown below via the Office electronic filing system.

Date

Dear Sir:

This is an appeal from the Office Action mailed on December 21, 2007, finally rejecting claims 1-34.

Fees

- Any required fee under 37 CFR § 41.20(b)(2) will be made at the time of submission via EFS-Web. In the event fees are not or cannot be paid at the time of EFS-Web submission, please charge any fees under 37 CFR § 1.17 which may be required to Deposit Account No. 13-3723.
- Please charge any additional fees associated with the prosecution of this application to Deposit Account No. 13-3723. This authorization includes the fee for any necessary extension of time under 37 CFR § 1.136(a). To the extent any such extension should become necessary, it is hereby requested.
- Please credit any overpayment to the same deposit account.

A Notice of Appeal in this application was mailed on March 12, 2008, and was received in the USPTO on March 12, 2008.

REAL PARTY IN INTEREST

The real party in interest is 3M Company (formerly known as Minnesota Mining and Manufacturing Company) of St. Paul, Minnesota and its affiliate 3M Innovative Properties Company of St. Paul, Minnesota.

RELATED APPEALS AND INTERFERENCES

Appellants are unaware of any related appeals or interferences.

STATUS OF CLAIMS

Claims 1-34 are pending in this application and are the subject of this appeal.

STATUS OF AMENDMENTS

No amendments have been filed after the final rejection.

SUMMARY OF CLAIMED SUBJECT MATTER

Respirator facepieces have been made from a soft compliant material, commonly rubber, that rests against the wearer's face and that forms a seal against the wearer's facial skin. The rubber typically is thick so that it can support filters and exhalation valves. See, for example, U.S. Patent 2,652,828 to Matheson and U.S. Patent 4,155,358 to McAlister et al. Thick rubber facepieces, however, can make the respirator heavy and uncomfortable to wear. Additionally, thick rubber adds to material and manufacturing costs. If the rubber is made thinner, however, the mask may have a tendency to collapse onto the user's face, particularly when tightening the harness while donning the respirator.

To make a facepiece lighter but not at the expense of reducing structural integrity, a thin rigid structural part has been incorporated into the facepiece. These rigid structural parts are commonly produced through injection molding and are often referred to as "rigid inserts". The rigid insert provides adequate structure for supporting filter cartridges and valves. A soft compliant material, which conforms to a person's face, is disposed on or about the rigid insert to enable the mask to fit snugly over the wearer's nose and mouth. The use of a rigid insert in conjunction with a soft compliant portion tends to make the mask lighter and more comfortable to wear, particularly when compared to the previous masks that had used thick rubber throughout

essentially the whole mask body to support the filter cartridges and valves. Masks that use a rigid insert in conjunction with a compliant face-contacting member are shown in U.S. Patent 6,016,804 to Gleason et al., U.S. Patent 5,592,937 to Freund, U.S. Patent 5,062,421 to Burns et al., and in U.S. Patent Application Serial No. 10/719,959 filed November 21, 2003, entitled "Respiratory Facepiece And Method Of Making A Facepiece Using Separate Molds."

Although masks that employ rigid inserts in conjunction with a soft compliant portion tend to be lighter and more comfortable to wear, they nonetheless can be somewhat more complicated to manufacture. Masks that use rigid inserts require multiple parts and the additional step of hermetically joining the insert to the soft, compliant, face-contacting portion.

The need for these additional parts and assembly steps can add to manufacturing costs. Applicants' invention provides a new respiratory mask that can overcome the need for thick facepieces, multiple parts, and multiple manufacturing steps to create the mask body. Unlike known respirators that used a thick rubber face piece to enable the cartridges to be adequately supported, the present invention may employ a thinner material that is sufficiently rigid and yet deformable at the cheeks so that the mask can adequately support filter cartridges and yet be sufficiently pliable to enable the mask to fit snugly and comfortably over a person's nose and at the cheek and chin portions. And unlike masks that used a rigid insert and a soft compliant portion, the present invention can make good contact to a wearer's face without using multiple facepiece parts and multiple manufacturing steps.

Applicants' invention provides a respiratory mask that comprises a mask body that lacks a rigid insert, that is non-elastomeric, and that is adapted for fitting over a person's nose and mouth. The mask body has a nose portion, a chin portion, first and second cheek portions, and an axis that extends from the nose portion to the chin portion.² The mask body is constructed to deform such that the first and second cheek portions can move towards each other about the axis when the mask body is held stationary and a force is exerted on the nose and chin portions.³ The respiratory mask also includes a harness that assists in supporting the mask on a wearer's face.4

¹ See page 2, lines 18-20; page 4, lines 10-14 and 19-22; page 5, lines 7-10; page 7, lines 24; page 8, lines 28-30;

page 11, lines 24-25; page 15, lines 4-5; and FIGs. 1-3.

See page 2, lines 20-22; page 3, lines 1-2, lines 23-26; page 4, lines 15-16; page 5, lines 7-10; page 6, lines 18-21; page 10, lines 25-26; page 15, lines 57-, and FIG. 3.

See page 2, lines 22-24; page 3, lines 2-5; page 2, lines 24-31; page 6, lines 18-27; page 15, lines 7-9; and FIGs. 2-

⁴ See page 2, lines 24-25; page 4, lines 4-5; page 5, lines 10-18; page 15, linc 10; and FIGs. 1-3.

As indicated, previously known masks achieved a good fit over the nose and around the cheeks and chin by using either thick elastomeric rubber or a rigid insert in conjunction with an elastomeric type face seal. Applicants' invention, in contrast, does not possess a rigid structural insert to enable filter elements and valves to be adequately attached to the mask body but yet is able to provide a good fit at the cheek regions of a wearer's face, as well as over the nose and around the chin. The inventive mask body also exhibits substantial deflection about an axis that extends from the nose portion to the cheek portion of the mask. When tension is placed upon the straps that support the mask body on a wearer's face, and an opposing force is exerted at the nose and chin portions — as would occur when the mask is being worn — the cheek portions deflect inwardly towards each other. This form of deflection enables a good fit to be achieved on the wearer's face. This fit can be maintained during jaw movement of the wearer. For example, if a mask user is speaking while wearing the mask, adequate contact between the mask and the cheek portions can still be achieved. When using the inventive mask, an extension of the jaw draws the cheek portions toward each other so that a tight fit is still maintained.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

First Ground of Rejection

Claims 1-5, 8, 29, and 32 have been rejected under 35 USC § 102(b), as being anticipated by U.S. Patent 4,960,121 to Nelson et al. (Nelson).

Second Ground of Rejection

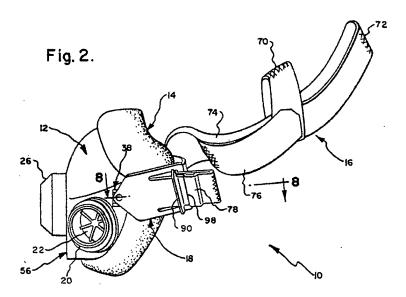
Claims 4, 6, 7, and 18 have been rejected under 35 USC § 103(a) as being unpatentable over the combined teachings of Nelson and U.S. Patent 6,062,221 to Brostrom et al. (Brostrom).

ARGUMENT

First Ground of Rejection

Applicants' invention requires a mask body that lacks a rigid insert and that is nonelastomeric. Applicants' mask body also is constructed to deform such that the first and second cheek portions can move towards each other about an axis when the mask body is held stationary and a force is exerted on the nose and chin portions.

Nelson's respiratory mask 10 includes a hard shell 12 and a face seal 14:



The hard shell 12 is molded from a suitable material such as an ABS plastic (column 2, lines 36-37), and the face seal 14 is noted as being elastomeric (column 2, lines 26-37). Because the combined hard shell 12 and elastomeric face seal 14 are the parts which would extend in spaced relationship away from a wearer's face during use to help define an interior gas space, these parts together meet the applicants' definition of a mask body. Applicants' have stated in their claim that the mask body lacks a rigid insert, which is defined as follows:

"Rigid insert" refers to a relatively stiff structural member that has been used on respiratory masks to provide adequate structure for attaching fluid communication components such as filter cartridges and exhalation valves while being joined to a more compliant mask body part that makes contact with and generally conforms to a wearer's face; and

It is apparent that Nelson's hard shell 12 meets applicants' definition of a rigid insert. Nelson's mask therefore includes both a rigid insert and an elastomeric member that extends in spaced relationship away from the wearer's face when the mask is being worn. The inclusion of these features is manifestly different from the invention being claimed by applicants in each of their independent claims. Further, there is no indication that Nelson's hard shell can be deformed such that the first and second cheek portions of the mask body can move towards each other about an axis when the mask is held stationary and a force is exerted on the nose and chin portions. More particularly, applicants' claim 19 specifies that the mask body of the invention is capable of

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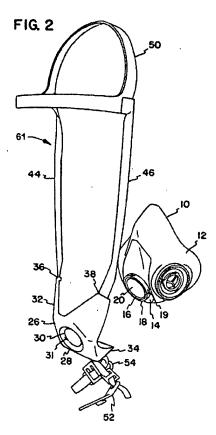
⁵ Applicants have defined "mask body" to mean the parts of a respiratory mask that extends in spaced relation away from a wearer's face during use and over their nose and mouth to help define an interior gas space that is separate from an exterior gas space.

exhibiting a deflection of at least 5 millimeters when an average force of 5 Newtons is applied to the mask body in accordance with the mask body deflection test. Claim 20 further indicates that the deflection would be at least 10 millimeters when such a force is applied. Nelson does not indicate that its mask body is capable of exhibiting such deflections when 5 Newtons of force is applied. Nor is there any evidence that such would be inherent in Nelson's mask.

Second Ground of Rejection

Applicants' invention provides a new respiratory mask that can overcome the need for thick facepieces, multiple parts, and multiple manufacturing steps to create the mask body. Unlike known respirators that used a thick rubber face piece to enable the cartridges to be adequately supported, applicants' invention may employ a thinner material that is sufficiently rigid and yet deformable at the cheeks so that the mask can adequately support filter cartridges and yet be sufficiently pliable to enable the mask to fit snugly and comfortably over a person's nose and at the cheek and chin portions. And unlike masks that used a rigid insert and a soft compliant portion, applicants' invention can make good contact to a wearer's face without using multiple facepiece parts and multiple manufacturing steps.

As indicated above, Nelson does not describe a respirator that lacks a rigid insert in its face piece. Brostrom adds little or nothing to the features that are missing in Nelson. In fact, Brostrom also describes a respirator that has a rigid insert incorporated into its mask body:



At column 3, lines 13-18, Brostrom indicates that the mask body 10 includes a seal portion 12 that "is configured to provide a seal against the face of the wearer" (this seal portion 12 is "constructed of a rubber-like material and is generally contoured to serve as a sealing surface) and further states that "[t]he central portion 14 is generally constructed of a rigid material and serves as a support for the seal portion 12." It is therefore apparent that Brostrom describes a respirator that also includes a rigid insert. Brostrom and Nelson therefore both fail to teach or suggest a respirator that lacks a rigid insert. Accordingly, these patents would not have led a person of ordinary skill to the subject matter of applicants' invention.

As indicated above, applicant's invention provides a respiratory mask that comprises a mask body that lacks a rigid insert, that is non-elastomeric, and that is adapted for fitting over a person's nose and mouth. The mask body has a nose portion, a chin portion, first and second cheek portions, and an axis that extends from the nose portion to the chin portion. The mask body is constructed to deform such that the first and second cheek portions can move towards each other about the axis when the mask body is held stationary and a force is exerted on the

nose and chin portions. The respiratory mask also includes a harness that assists in supporting the mask on a wearer's face.

Previously known masks achieved a good fit over the nose and around the cheeks and chin by using either thick elastomeric rubber or a rigid insert in conjunction with an elastomeric type face seal. Applicants' invention, in contrast, does not possess a rigid structural insert to enable filter elements and valves to be adequately attached to the mask body but yet is able to provide a good fit at the cheek regions of a wearer's face, as well as over the nose and around the chin. The inventive mask body exhibits substantial deflection about an axis that extends from the nose portion to the check portion of the mask. When tension is placed upon the straps that support the mask body on a wearer's face, and an opposing force is exerted at the nose and chin portions — as would occur when the mask is being worn — the cheek portions deflect inwardly towards each other. This form of deflection enables a good fit to be achieved on the wearer's face. This fit can be maintained during jaw movement of the wearer. For example, if a mask user is speaking while wearing the mask, adequate contact between the mask and the cheek portions can still be achieved. When using the inventive mask, an extension of the jaw draws the cheek portions toward each other so that a tight fit is still maintained. The Nelson/Brostrom combination does not suggest a respirator that meets the structural features of applicants' invention as recited in the independent claims; nor does it describe a respirator that exhibits the benefits provided by applicants' respirator.

In regard to the dependent claims, the noted deflection can be achieved when little force is applied to the mask — see claims 19, 20, and 34. Nelson and Brostrom both fail to provide any indication of such an ability. Further, these patents also fail to teach or suggest a mask body that lacks a rigid insert and that has the flexural modulus of claims 14-17, 13, and 33. Nor do Nelson and Brostrom teach or suggest that the mask body can lack a rigid insert but also be light in weight as recited in claims 21-24 and 33.

In short, the structure and other features and advantages of the invention are not taught or suggested by the prior art. As such, applicants' invention is new and nonobvious, and the inventors should be awarded a patent for their new teachings.

CONCLUSION

For the foregoing reasons, appellants respectfully submit that the Examiner has erred in rejecting this application. Please reverse the Examiner on all counts.

Respectfully submitted,

June 12, 2008

Date

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Office of Intellectual Property Counsel 3M Innovative Properties Company Facsimile No.: 651-736-3833

CLAIMS APPENDIX

- 1. A respiratory mask that comprises:
- (a) mask body that lacks a rigid insert, that is non-elastomeric, and that is adapted for fitting over a person's nose and mouth, the mask body having a nose portion, a chin portion, first and second cheek portions, and an axis that extends from the nose portion to the chin portion, the mask body being constructed to deform such that the first and second cheek portions can move towards each other about the axis when the mask body is held stationary and a force is exerted on the nose and chin portions; and
 - (b) a harness that assists in supporting the mask on a wearer's face.
 - 2. The respiratory mask of claim 1, further comprising:
 - (c) one or more filter cartridges that are attached to the mask body.
- 3. The respiratory mask of claim 2, wherein the mask includes first and second filter cartridges that are secured to the first and second cheek portions, respectively.
- 4. The respiratory mask of claim 3, further comprising an exhalation valve that is located at a central portion of the mask body, and wherein the harness includes a carriage and at least one strap, the carriage covering the exhalation valve and being secured to the mask body at the central portion.
- 5. The respiratory mask of claim 1, wherein the first and second cheek portions are capable of deflecting inward during normal jaw movement of the wearer.

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6. The respiratory mask of claim 1, wherein the harness includes a carriage and at least one strap, the strap(s) being joined to the carriage, and the carriage being centrally mounted to the mask body, the first and second cheek portions of the mask body being capable of being deflected inwards toward the respective cheeks on a wearer in response to tension from the strap(s) when the mask is being worn.

- 7. The respiratory mask of claim 6, further comprising first and second filter cartridges that are secured to the first and second cheek portions of the mask body, wherein the first and second filter cartridges move inwardly with the first and second cheek portions when deflection occurs as a result of a force exerted on the nose and chin portions from tension on the at least one strap when the mask is worn.
- 8. The respiratory mask of claim 1, wherein the mask body further includes a soft deformable material as a face seal, which soft deformable material is secured to a perimeter of the mask body to improve fit of the mask body to a person's face.
- 9. The respiratory mask of claim 8, wherein the mask body has a foam material secured to the interior of the mask body at the nose portion.
- 10. The respiratory mask of claim 1, wherein the mask body has a mechanism that allows for attachment of a powered air supply source.
- 11. The respiratory mask of claim 1, wherein the mask body has an elongation at its elastic limit of less than about 5 percent.
- 12. The respiratory mask of claim 1, wherein the mask body has an elongation at its elastic limit of less than about 2 percent.
- 13. The respiratory mask of claim 1, wherein the mask body has an elongation at its elastic limit of less than about 1 percent.
- 14. The respiratory mask of claim 1, wherein the material from which the mask body is made has a flexural modulus greater than 50 MPa.

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- 15. The respiratory mask of claim 14, wherein the material from which the mask body is made has a flexural modulus greater than 500 MPa.
- 16. The respiratory mask of claim 15, wherein the material from which the mask body is made has a flexural modulus greater than 1000 MPa.
- 17. The respiratory mask of claim 16, wherein the material from which the mask body is made has a flexural modulus less than about 4000 MPa.
- 18. The respiratory mask of claim 6, wherein the strap(s) is capable of applying a force of about 10 to 20 N when the mask is fitted on a wearer's face.
- 19. The respiratory mask of claim 1, wherein the mask body is capable of exhibiting a deflection of at least 5 mm when an average force of 5 N is applied to the mask body in accordance with the mask body deflection test.
- 20. The respiratory mask of claim 1, wherein the mask body is capable of exhibiting a deflection of at least 10 mm when an average force of 5 N is applied to the mask body in accordance with the mask body deflection test.
- 21. The respiratory mask of claim 1, wherein the mask body in naked form does not weigh more than about 35 grams.
- 22. The respiratory mask of claim 1, wherein the mask body in naked form does not weigh more than 30 grams.
- 23. The respiratory mask of claim 1, wherein the mask body in naked form does not weigh more than 25 grams.
- 24. The respiratory mask of claim 23, wherein the mask body in naked form does not weigh more than 10 grams.
- 25. The respiratory mask of claim 1, wherein the mask body has an average thickness less than about 2 mm.

26. The respiratory mask of claim 1, wherein the mask body has an average thickness less than 1.6 mm.

- 27. The respiratory mask of claim 1, wherein the mask body has an average thickness less than 1.2 mm.
- 28. The respiratory mask of claim 27, wherein the mask body has an average thickness greater than about 0.5 mm.
- 29. The respiratory mask of claim 1, wherein the mask body is constructed from a thermoformed plastic.
- 30. The respiratory mask of claim 29, wherein the thermoformed plastic comprises polypropylene.
- 31. The respiratory mask of claim 1, wherein the mask body in naked form weighs less than 35 g, has an average thickness less than 2 mm, and has a flexural modulus greater than 500 MPa.
- 32. A mask body that lacks a rigid insert, that is non-elastomeric, and that is adapted for fitting over a person's nose and mouth, the mask body comprising a nose portion, a chin portion, first and second cheek portions, and an axis that extends from the nose portion to the chin portion, the mask body being constructed to deform such that the first and second cheek portions can move towards each other about the axis when a force is exerted.
 - 33. A method of making a respiratory mask, which method comprises:

forming a mask body not weighing more than 35 g from a non-elastomeric plastic material that has a flexural modulus of greater than 500 MPa, the mask body being formed to a cup shape that has an average thickness less than 2 mm and that is adapted for fitting over a person's nose and mouth without inclusion of a rigid insert but with an integrally-formed nose portion, chin portion, central portion, and first and second cheek portions;

and securing a harness to the mask body.

34. The method of claim 33, wherein the mask body exhibits a deflection of at least 5 mm when a force of 5 N is applied to the mask body when tested in accordance with the Mask Body Deflection Test.

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EVIDENCE APPENDIX

None.

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RELATED PROCEEDINGS APPENDIX

None.